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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/014,291

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Stephan von Horsten

20488/12 U.S.

9996

7590

01/19/2006

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/014,291	HORSTEN ET AL	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) -7 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 and 13 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 9-12 and 14 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 1-2, 5 and 13 have been amended as requested in the amendment filed on December 16, 2005. Following the amendment, claims 1-7 and 9-15 are pending in the instant application.

Claims 1-7 and 9-15 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on December 16, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Claim Objections***

5. Claim 15 is objected to because of the following informalities: claim 15 does not end with a period (see MPEP 608.01(m), Form of Claims). Appropriate correction is required.

### ***Double Patenting***

6. Claims 1, 2-4, 6-7, 9-12 and 14, as amended, stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,319,893 ('893 Patent) for reasons of record in previous office communications.

Applicant traverses the rejection on the premises that “hypoglycemia is not consistently or inherently associated with anxiety” (bottom at page 4 of the Response) and, further, that “inherency is not the correct test for obviousness-type double patenting” (top at page 5).

Applicant refers to case law *Georgia-Pacific Corp. v. United States Gypsum Co.*, *In re Longi et al.* and *Rapoport v. Dement* (middle at page 5). Applicant submits that “purposeful treatment of anxiety is an intent to treat the underlying condition of anxiety and it is not an intent to raise the blood sugar level” (bottom at page 6 of the Response). Applicant’s arguments have been fully considered but are not persuasive for the following reasons.

Applicant’s statement that inherency is not the correct test for obviousness-type double patenting is not completely accurate. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). In other words, the proper test of obvious-type double patenting rejection is whether the instant claims encompass an obvious embodiment of the patented claims. Here, claims 1-4 of U.S. Patent No. 6,319,893 recite a method of raising the blood sugar level in a mammal having hypoglycemia by administration of an inhibitor of DP IV enzyme. The method of claims 1-4 of ‘893 Patent differs from claims 1, 2-4, 6-7, 9-12 and 14 herein because the instant claims state a different intent of use of inhibitors of DP IV, such as for raising blood sugar level as compared to treatment of anxiety. However, a skilled practitioner readily appreciates that symptoms of hypoglycemia, a

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clinical syndrome that results from low blood sugar, include anxiety, sweating, tremor, palpitations, nausea, and pallor. Thus, contrary to Applicant's statement that "hypoglycemia is not consistently or inherently associated with anxiety" (bottom at page 4 of the Response), anxiety is a part of so called neurogenic (or sympathetic) first set of physiological response to low blood sugar levels. Furthermore, '893 Patent is not limited to treating hypoglycemic conditions in which anxiety component is not present. Therefore, treating anxiety by administration of DP IV inhibitors, as currently claimed, is obvious over treatment of hypoglycemia-induced anxiety by administration of DP IV inhibitors, as disclosed in '893 Patent. Thus, claims 1-4 directed to a method of treatment of hypoglycemia in '893 Patent encompass treatment of hypoglycemia-induced anxiety, which is an embodiment also encompassed by the instant claims directed to treatment of anxiety, including anxiety associated with hypoglycemia.

### ***Conclusion***

7. Claims 5 and 13 are allowed. Claim 15 is objected to. Claims 1-4, 6, 7, 9-12 and 14 are rejected.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period


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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1649

January 18, 2006